



## General

### Guideline Title

Screening for autism spectrum disorder in young children: U.S. Preventive Services Task Force recommendation statement.

### Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for autism spectrum disorder in young children: U.S. Preventive Services Task Force recommendation statement. JAMA. 2016 Feb 16;315(7):691-6. [22 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Recommendations

### Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the levels of certainty regarding net benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

#### Summary of Recommendation and Evidence

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for autism spectrum disorder (ASD) in young children for whom no concerns of ASD have been raised by their parents or a clinician. (I statement)

#### Clinical Considerations

##### Patient Population Under Consideration

This recommendation applies to children who have not been diagnosed with ASD or developmental delay and for whom no concerns of ASD have been raised by parents, other caregivers, or health care professionals.

##### Screening Tests

A number of tests are available for screening for ASD in children younger than 30 months. The most commonly studied tool is the Modified Checklist for Autism in Toddlers (M-CHAT) and its subsequent revisions (Modified Checklist for Autism in Toddlers with Follow-Up [M-CHAT-F] and Modified Checklist for Autism in Toddlers–Revised, with Follow-Up [M-CHAT-R/F]). The M-CHAT-R/F is a parent-rated scale, and a positive finding leads to a follow-up interview. If the follow-up interview is positive, a full diagnostic workup for ASD is indicated. The

screening process assesses communication skills, joint attention, repetitive movement, and pretend play.

## Treatments and Interventions

Treatments for ASD include behavioral, medical, educational, speech/language, and occupational therapy and complementary and alternative medicine approaches. Treatments for young children in the target age group for routine screening for ASD are primarily behavioral interventions, particularly early intensive behavioral and developmental interventions, which may include approaches incorporating applied behavior analysis principles, parent training components, and play- or interaction-based interventions. Among the behavioral interventions, those based on applied behavior analysis have the highest-quality data supporting their effects on cognitive and language outcomes. These interventions can be delivered in a home or school setting and are generally time-intensive, with some programs requiring up to 40 hours a week.

## Suggestions for Practice Regarding the I Statement

### *Potential Preventable Burden*

Autism spectrum disorder can cause significant social, communication, and behavioral challenges for affected children and place substantial strain on family members and other caregivers. Treatment and maturation may reduce the effects of the core symptoms of ASD for some children, but others may experience long-term effects on education, employment, and ability to live independently. It is important that clinicians listen carefully to parents when concerns are raised by the parents or during an examination and make prompt use of validated tools to assess the need for further diagnostic testing and services. Disparities have been observed in the frequency and age at which ASD is diagnosed among children by race/ethnicity, socioeconomic status, and language of origin, creating concern that certain groups of children with ASD may be systematically underdiagnosed. It is important to note that an I statement is not a recommendation for or against screening. In the absence of evidence about the balance of benefits and harms, clinicians should use their clinical judgment to decide if screening in children without overt signs and symptoms is appropriate for the population in their care.

### *Potential Harms*

Although there is limited evidence about the harms of screening for ASD in children, reported potential harms include misdiagnosis and the anxiety associated with further testing after a positive screening result, particularly if confirmatory testing is delayed because of resource limitations. Behavioral treatments are not generally thought to be associated with significant harms but can place a large time and financial burden on the family. Other treatments for ASD are less well studied and were not included in this review.

### *Current Practice*

A 2004 survey of pediatricians in Maryland and Delaware found that 8% screened specifically for ASD. Few data are available regarding the current prevalence of screening for ASD by clinicians in the United States. More recent surveys have found higher rates, although they remain less than 60%.

## Useful Resources

The Centers for Disease Control and Prevention provides Web-based continuing education for clinicians called Autism Case Training (available at <http://www.cdc.gov/ncbddd/actearly/autism/case-modules/index.html>), as well as other information about ASD for families (available at <http://www.cdc.gov/ncbddd/autism/families.html>).

The Health Resources and Services Administration's Web site provides links to training resources for professionals (available at <http://mchb.hrsa.gov/programs/autism/trainingforprofessionals.html>).

The M-CHAT screening tool is available online for free at <https://m-chat.org/>. Other professional and advocacy organizations have also developed toolkits and resources.

The USPSTF has made a recommendation on screening for speech and language delays and disorders among children 5 years or younger (see the National Guideline Clearinghouse [NGC] summary of the USPSTF guideline [Screening for speech and language delay and disorders in children aged 5 years or younger: U.S. Preventive Services Task Force recommendation statement](#)).

## Definitions

### What the USPSTF Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice

A Grade	Grade Definitions	Offer/provide this service. Suggestions for Practice
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

#### USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> <li>• The number, size, or quality of individual studies</li> <li>• Inconsistency of findings across individual studies</li> <li>• Limited generalizability of findings to routine primary care practice</li> <li>• Lack of coherence in the chain of evidence</li> </ul> <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> <li>• The limited number or size of studies</li> <li>• Important flaws in study design or methods</li> <li>• Inconsistency of findings across individual studies</li> <li>• Gaps in the chain of evidence</li> <li>• Findings not generalizable to routine primary care practice</li> <li>• A lack of information on important health outcomes</li> </ul> <p>More information may allow an estimation of effects on health outcomes.</p>

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Autism spectrum disorder (ASD)

### Guideline Category

Screening

### Clinical Specialty

Family Practice

Neurology

Pediatrics

### Intended Users

Advanced Practice Nurses

Health Care Providers

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Public Health Departments

### Guideline Objective(s)

To provide new U.S. Preventive Services Task Force (USPSTF) recommendations on screening for autism spectrum disorder (ASD) in young children

### Target Population

Children aged 18 to 30 months who have not been diagnosed with autism spectrum disorder (ASD) or developmental delay and for whom no concerns of ASD have been raised by parents, other caregivers, or health care professionals

### Interventions and Practices Considered

Screening for autism spectrum disorder (ASD)

## Major Outcomes Considered

- Key Question 1: Is screening for autism spectrum disorder (ASD) conducted in children 12 to 36 months old associated with improved short- and long-term outcomes?
- Key Question 2: What are the performance characteristics (e.g., sensitivity, specificity, positive predictive value [PPV], and negative predictive value [NPV]) of ASD screening tests in children 12 to 36 months old?
  - a. Do certain risk factors (e.g., prematurity or having a sibling diagnosed with ASD) modify the performance characteristics of ASD screening tests?
  - b. Does the age at which ASD screening is performed modify the performance characteristics of ASD screening tests?
  - c. Do other characteristics of the child or family (e.g., intellectual disability, socioeconomic status [SES], literacy level, insurance status, race/ethnicity, sex, primary language spoken in home, limited English proficiency) modify the performance characteristics of ASD screening tests?
- Key Question 3: What are the harms (e.g., distress, potential misclassification) of ASD screening for the child and family?
- Key Question 4: What is the effect of interventions targeting young children (in preschool and elementary school) on the following outcomes: core ASD symptoms, cognitive and intellectual functioning, language and communication skill development, challenging behavior, adaptive behavior, educational placement/achievement, and quality of life for the child and family?
  - a. What is the effect of intervention timing (by age and in relation to the establishment of a definitive diagnosis) on treatment outcomes?
  - b. What is the effect of severity of ASD (as reported in each study) on treatment outcomes?
- Key Question 5: What are the harms of treatment for ASD in young children?

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): An evidence synthesis was performed by the Vanderbilt Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

#### Data Sources and Searches

Search Strategy

*Databases*

A librarian employed search strategies, provided in Appendix A of the evidence synthesis, to retrieve research on screening for autism spectrum disorder (ASD) in young children and interventions for young children with ASD. All strategies were peer reviewed by a second librarian. The primary literature search for screening-related studies employed four databases: MEDLINE® via the PubMed interface, PsycINFO (psychology and psychiatry literature), the Educational Resources Information Clearinghouse, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) database. The search for intervention studies used the same databases with the exception of CINAHL. In the tests of the strategies, searching CINAHL did not retrieve any unique treatment studies, thus the investigators did not use it for the treatment search.

Search strategies used a combination of subject heading terms appropriate for each database and key words relevant screening or intervention for ASD. The investigators limited searches to literature published since 2000 to ensure that screening methods and interventions used currently would be represented. They also manually searched the reference lists of included studies and of recent narrative and systematic reviews and meta-analyses addressing ASD screening or intervention in young children with ASD.

*Prior Systematic Reviews and Meta-Analyses*

The investigators identified systematic reviews and meta-analyses retrieved by the searches for primary literature as well as through scanning the reference lists of included studies. The investigators included summaries of reviews and meta-analyses they rated as good quality (see the "Quality Assessment and Data Extraction" section in the "Description of the Methods Used to Analyze the Evidence" field).

### *Search Terms and Dates*

Controlled vocabulary terms served as the foundation of the search for screening-related literature in each database (e.g., MEDLINE vocabulary terms including mass screening, early diagnosis), complemented by additional keyword phrases (e.g., screening, identification). To locate intervention-related studies, the investigators used the search strategy employed in the prior review of therapies for children with ASD. The search used both controlled vocabulary and keyword terms (see Appendix A in the evidence synthesis). They also limited searches for screening and intervention studies to items published in English and from 2000 to the present. The searches were done between January and December 2013 for screening literature and December 2013 for intervention studies. The investigators updated the MEDLINE search for screening and intervention studies in August 2014. They imported all citations into an electronic database.

### Study Selection

#### *Inclusion and Exclusion Criteria*

The investigators developed criteria for inclusion and exclusion in consultation with the Medical Officer and USPSTF members (see Table 1 in the evidence synthesis).

#### *Criteria for Screening Studies*

Screening-related studies needed to include at least two individuals (i.e., excluding single case reports) screened for ASD between the ages of 12 and 36 months. The investigators required that studies include undiagnosed populations or populations without suspected developmental delay (i.e., they excluded studies in which the majority of children had an already identified concern about potential developmental delay by parents or clinicians underlying referral for screening/evaluation) or who were already diagnosed with ASD. There is an additional body of research on assessing the ability of ASD screening tests to accurately identify children with ASD in groups of children suspected as having some sort of delay, and as expected, the test performance characteristics are better in these studies than those seen in a general screening population. There is also a body of evidence in which samples are selected that include children with known diagnoses of ASD; these are intended to assess the ability of the screeners to discriminate, but the investigators did not consider that the performance characteristics would apply to the primary care population. None of these scenarios reflects screening in the absence of any concern in the primary care office, in which many children are unrecognized as having symptoms of delay.

The investigators assessed both intermediate and health-related outcomes. Intermediate outcomes included timing of referral and diagnosis and timing of access to intervention. Health-related outcomes included effects on core ASD symptoms, language and communication skill development, and quality of life for the child and caregiver. Screening studies had to take place in primary care or primary care relevant settings.

#### *Criteria for Treatment Studies*

To complete the clinical logic of screening to achieve earlier diagnosis and treatment in order to achieve improved health outcomes, the investigators updated a previously published review of treatment for children with ASD by supplementing it with newer literature meeting the following criteria: 1) treatment studies needed to include at least 10 individuals with ASD; 2) report on an intervention aimed at young children with ASD (between the ages of 0 and 5 years) and include a comparison group; and 3) studies had to evaluate outcomes related to core ASD symptoms, cognitive and intellectual functioning, language and communication skill development, challenging behavior, adaptive behavior, educational placement/achievement, harms of intervention, or quality of life for the child and family. The investigators included studies with any length of followup and in any setting (clinic, home). They briefly summarized findings of studies addressing interventions under Key Question (KQ) 4.

#### *Screening of Studies*

Once the investigators identified articles through the electronic database searches, review articles, and bibliographies, they examined abstracts of articles to determine whether studies met the criteria. Two reviewers separately evaluated each abstract for inclusion or exclusion, using an Abstract Review Form (see Appendix B in the evidence synthesis). If one reviewer concluded that the article could be eligible for the review based on the abstract, the investigators retained it for full text assessment.

Two reviewers independently assessed the full text of each included study using a standardized form (see Appendix B in the evidence synthesis) that included questions stemming from the inclusion/exclusion criteria. Disagreements between reviewers were resolved by a third-party adjudicator. The group of abstract and full text reviewers included expert clinicians and health services researchers.

## Literature Search Results

### Screening Studies

The investigators identified 3,469 citations potentially addressing screening for ASD. They excluded 3,050 publications at the abstract review stage and 435 at the full text stage (see Appendix E in the evidence synthesis). The investigators summarize results from 17 unique studies (reported in 22 publications; one publication reports two separate studies) meeting the inclusion criteria in this review. Figure 2 in the evidence synthesis outlines the disposition of screening studies in primary care settings. They also summarize information about studies identified for the treatment-related KQs (4 and 5).

### Intervention Studies

The investigators identified 2,639 citations and abstracts (see Figure 3 in the evidence synthesis). They excluded 2,012 studies at abstract review and assessed the full text of 627 studies. Among these, 55 publications, comprising 42 unique studies, met the criteria for intervention studies and were rated as good or fair quality. These studies included 26 RCTs (nine good and 17 fair quality), five nonrandomized trials (one good and four fair quality), 10 prospective studies (two good and eight fair quality), and one retrospective cohort study (fair quality).

## Number of Source Documents

### Screening Studies (Key Questions 1 to 3)

Seventeen studies were included in the qualitative synthesis (comprising 22\* unique studies) were included:

- Key Question 1: 0
- Key Question 2: 17
- Key Question 2a-c: 1
- Key Question 3: 0

\*One paper reported 2 unique studies; 3 studies comprised multiple publications.

### Intervention Studies (Key Questions 4 and 5)

Fifty-five early intensive behavioral and developmental intervention studies (comprising 42 unique studies) were included (Key Question 4).

No studies of behavioral interventions reported harms (Key Question 5).

See Figures 2 and 3 in the evidence synthesis (see the "Availability of Companion Documents" field) for dispositions of screening and intervention studies identified.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

#### Quality Levels

Good: Evaluates relevant available screening test; uses a credible reference standard; interprets reference standard independently of screening test; reliability of test assessed; has few or handles indeterminate results in a reasonable manner; includes large number (>1000) of patients with and without disease, includes participants drawn from the general population and follows at least a random sample of screen-negative participants.

Fair: Evaluates relevant available screening test; uses reasonable although not best standard; interprets reference standard independent of screening test; moderate sample size.

Poor: Has fatal flaw such as: uses inappropriate reference standard; screening test improperly administered; biased ascertainment of reference standard; very small sample size.

# Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): An evidence synthesis was performed by the Vanderbilt Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

### Quality Assessment and Data Extraction

#### Data Extraction and Data Management

The staff members and clinical experts who conducted the review jointly developed the evidence table, which was used to summarize data from the studies. They modeled the table on USPSTF methods guidelines and designed the table to include issues of study design, descriptions of the study populations, description of the screening process or intervention, and baseline and outcome data on constructs of interest.

One team member initially entered information into the evidence table. Another member of the team also independently reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The full research team met during the article extraction period and discussed issues related to data extraction (e.g., optimal level of detail in the description of the screening technique or intervention, determining key population characteristic to include). In addition to outcomes related to screening performance and intervention effectiveness, they extracted all data available on harms. Harms encompass the full range of specific negative effects, including the narrower definition of adverse events. The final evidence table is presented in Appendix C of the evidence synthesis. Studies are presented in the evidence table alphabetically by the last name of the first author within each year.

#### Quality (Risk of Bias) Assessment of Individual Studies

##### *Screening Studies*

The investigators assessed the quality of screening studies using design-specific quality criteria based on the USPSTF methods.

##### *Intervention Studies*

The investigators assessed the quality of intervention studies using methods previously developed for systematic reviews of interventions for children with ASD. They evaluated the quality of studies in the domains below using specific questions to evaluate a study's conduct. The investigators rated each domain individually and combined them for an overall quality level. Three levels were possible: good, fair, and poor.

Finally, the investigators assessed the quality of systematic reviews and meta-analyses using the AMSTAR tool. For all types of studies, two reviewers independently assessed quality, with final decisions made via discussion to reach consensus or by third-party adjudication by a senior methodologist as needed. They reported individual quality assessments for each study in Appendix D in the evidence synthesis.

#### Determining Quality Levels

##### *Screening Studies*

The investigators determined quality ratings for screening studies based on USPSTF methods and criteria for ratings for diagnostic accuracy studies (see the "Rating Scheme for the Strength of the Evidence" field).

An important consideration in assessing quality of the screening accuracy studies was the methodology employed for handling screen-negative participants. Given the prevalence rate of 1 in 68, as well as the resource-intensive nature of conducting the gold standard evaluations (i.e., in-person, time-intensive diagnostic assessments by skilled behavioral professionals sometimes lasting a full day or more) in screen-negative children, almost no study has followed a large enough sample to truly assess false negatives on a population level. Given the pervasive and ongoing nature of developmental disorders, however, false negatives are primarily a concern among borderline cases, such as those that fail one portion of the screening process. Rather than follow up with all screen negatives, some studies followed up with borderline cases that failed a portion of the screening process (e.g., failed the screener but not the interview). As such, the investigators allowed varying methodologies for attempting to assess false negatives among those who partially failed screening to qualify in determination of a "good" study if they met other criteria as a good study.

##### *Intervention Studies*



The investigators assessed each domain (described in the "Quality [Risk of Bias] Assessment of Individual Studies" section of the evidence synthesis) individually and considered the individual ratings to determine an overall quality assessment of good, fair, or poor (see the "Rating Scheme for the Strength of the Evidence" field). They required that studies receive positive scores questions related to study design and diagnostic approach to be considered good quality. Scores were calculated first by domain and then summed and weighted as described in Table 2 of the evidence synthesis to determine overall study quality. Studies could receive up to two points on the domains of study design, diagnostic approach, participant ascertainment, and intervention, and up to one point on the domains of outcome measurement and statistical analysis.

Data Synthesis and Analysis

The investigators determined that a meta-analysis of screening studies would be inappropriate and unnecessary. They assessed attrition at each step in the process and assumed nondifferential loss to followup to impute diagnostic yield and other outcomes if there had been complete followup for key studies. The investigators analyzed results of studies qualitatively, summarizing them in tables and in text. They summarized only those systematic reviews rated as good quality.

Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

U.S. Preventive Services Task Force Recommendation Grid\*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

\*A, B, C, D, and I (*Insufficient*) represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the USPSTF constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the

evidence?)

5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term certainty will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of the Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med*. 2007;147(12):871-875. [5 references].

## I Statements

For I statements, the USPSTF has a plan to commission its Evidence-based Practice Centers (EPCs) to collect information in 4 domains pertinent to clinical decisions about prevention and to report this information routinely. This plan is described in the paper: Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. *Ann Intern Med*. 2009;150:199-205. [www.annals.org](http://www.annals.org)

The first domain is potential preventable burden of suffering from the condition. When evidence is insufficient, provision of an intervention designed to prevent a serious condition (such as dementia) might be viewed more favorably than provision of a service designed to prevent a condition that does not cause as much suffering (such as rash). The USPSTF recognized that "burden of suffering" is subjective and involves judgment. In clinical settings, it should be informed by patient values and concerns.

The second domain is potential harm of the intervention. When evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television). The USPSTF again acknowledges the subjective nature and the difficulty of assessing potential harms: for example, how bad is a "mild" stroke?

The third domain is cost—not just monetary cost, but opportunity cost, in particular the amount of time a provider spends to provide the service, the amount of time the patient spends to partake of it, and the benefits that might derive from alternative uses of the time or money for patients, clinicians, or systems. Consideration of clinician time is especially important for preventive services with only insufficient evidence because

providing them could "crowd out" provision of preventive services with proven value, services for conditions that require immediate action, or services more desired by the patient. For example, a decision to routinely inspect the skin could take up the time available to discuss smoking cessation, or to address an acute problem or a minor injury that the patient considers important.

The fourth domain is current practice. This domain was chosen because it is important to clinicians for at least 2 reasons. Clinicians justifiably fear that not doing something that is done on a widespread basis in the community may lead to litigation. More important, addressing patient expectations is a crucial part of the clinician–patient relationship in terms of building trust and developing a collaborative therapeutic relationship. The consequences of not providing a service that is neither widely available nor widely used are less serious than not providing a service accepted by the medical profession and thus expected by patients. Furthermore, ingrained care practices are difficult to change, and efforts should preferentially be directed to changing those practices for which the evidence to support change is compelling.

Although the reviewers did not explicitly recognize it when these domains were chosen, the domains all involve consideration of the potential consequences—for patients, clinicians, and systems—of providing or not providing a service. Others writing about medical decision making in the face of uncertainty have suggested that the consequences of action or inaction should play a prominent role in decisions.

## Rating Scheme for the Strength of the Recommendations

### What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

### USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the

Level of Certainty	Description
	<p>estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> <li>• The number, size, or quality of individual studies</li> <li>• Inconsistency of findings across individual studies</li> <li>• Limited generalizability of findings to routine primary care practice</li> <li>• Lack of coherence in the chain of evidence</li> </ul> <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> <li>• The limited number or size of studies</li> <li>• Important flaws in study design or methods</li> <li>• Inconsistency of findings across individual studies</li> <li>• Gaps in the chain of evidence</li> <li>• Findings not generalizable to routine primary care practice</li> <li>• A lack of information on important health outcomes</li> </ul> <p>More information may allow an estimation of effects on health outcomes.</p>

## Cost Analysis

The U.S. Preventive Services Task Force (USPSTF) does not consider the costs of providing a service in this assessment.

## Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

### Peer Review

Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center (EPC) and the Agency for Healthcare Research and Quality (AHRQ) send the draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. The draft evidence review is also posted on the USPSTF Web site for public comment. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

### Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from August 4, 2015, to August 31, 2015. Many parents of children with autism spectrum disorder (ASD), adults with ASD, and clinicians who care for children with ASD wrote to share their personal experiences and concerns. One major area of concern was a perception that the USPSTF was advocating against screening or against the use of screening tools to follow up on parents' concerns. This was not the USPSTF's intention, and the USPSTF will be clear when communicating this recommendation that it is not recommending for or against screening but advocating for more research. In the meantime, clinicians should use their clinical judgment, especially when caring for populations in which case-finding may be difficult because of language, access, or other barriers. Furthermore, clinicians should listen carefully to parents' concerns and use validated tools to assess whether further diagnosis or services are needed. Standardized tools, such as the Modified Checklist for Autism in Toddlers (M-CHAT), may be used

diagnostically to follow up on concerns expressed by parents.

Another area of concern was why studies of test accuracy and the effectiveness of treatment were not sufficient to support screening and what kind of research would be needed to support a positive recommendation. In response, the USPSTF revised the recommendation statement to clarify the lack of treatment studies in the population that would likely be identified through screening and to provide greater detail about the different types of studies that could fill this evidentiary gap. Finally, other comments focused on the low cost and lack of harms associated with screening. The USPSTF revised the recommendation statement to clarify that, while the screening tools are relatively easy to administer and behavioral interventions are generally safe, the potential effects of extended treatment, in the absence of clear benefit, on families in terms of time and resources are not negligible.

#### Comparison with Guidelines from Other Groups

Recommendations for screening from the following groups were discussed: the American Academy of Pediatrics' Bright Futures, the American Academy of Family Physicians, the American Academy of Neurology, the Child Neurology Society, the American Academy of Child and Adolescent Psychiatry, and the UK National Screening Committee.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

#### Benefits of Early Detection and Intervention or Treatment

The U.S. Preventive Services Task Force (USPSTF) found inadequate direct evidence on the benefits of screening for autism spectrum disorder (ASD) in toddlers and preschool-age children for whom no concerns of ASD have been raised by family members, other caregivers, or health care professionals. There are no studies that focus on the clinical outcomes of children identified with ASD through screening. Although there are studies suggesting treatment benefit in older children identified through family, clinician, or teacher concerns, the USPSTF found inadequate evidence on the efficacy of treatment of cases of ASD detected through screening among very young children. Treatment studies were generally very small, few were randomized trials, most included children who were older than would be identified through screening, and all were in clinically referred rather than screen-detected patients.

### Potential Harms

#### Harms of Early Detection and Intervention or Treatment

The U.S. Preventive Services Task Force (USPSTF) found that the harms of screening for autism spectrum disorder (ASD) and subsequent interventions are likely to be small based on evidence about the prevalence, accuracy of screening, and likelihood of minimal harms from behavioral interventions.

## Qualifying Statements

### Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without obvious related signs or symptoms.

- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services.

## Implementation of the Guideline

### Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its [Web site](#) . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

### Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.



# Categories

## IOM Care Need

Staying Healthy

## IOM Domain

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for autism spectrum disorder in young children: U.S. Preventive Services Task Force recommendation statement. JAMA. 2016 Feb 16;315(7):691-6. [22 references] [PubMed](#)

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2016 Feb 16

## Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

## Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

## Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality (AHRQ) support the operations of the USPSTF.

## Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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\*Members of the USPSTF at the time this recommendation was finalized. For a list of current Task Force members, go to <http://www.uspreventiveservicestaskforce.org/Page/Name/our-members> .

## Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

### Conflict of Interest Disclosures

All authors have completed and submitted the International Committee of Medical Journal Editors (ICMJE) Form for Disclosure of Potential Conflicts of Interest. Dr Bibbins-Domingo reported having received grants from the National Institutes of Health and Centers for Disease Control and Prevention and other support from the Institute for Clinical and Economic Review. No other disclosures were reported. Authors followed the policy regarding conflicts of interest described at <http://www.uspreventiveservicestaskforce.org/Page/Name/conflict-of-interest-disclosures> .

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the [Journal of the American Medical Society \(JAMA\) Web site](#) .

## Availability of Companion Documents

The following are available:

### Evidence Review:

- McPheeters ML, Weitlauf A, Vehorn A, Taylor C, Sathe NA, Krishnaswami S, Fonnesebeck C, Warren ZE. Screening for autism spectrum disorder in young children: a systematic evidence review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 129. AHRQ Publication No. 13-05185-EF-1. Rockville (MD): Agency for Healthcare Research and Quality; 2016 Feb. 220 p. Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#) .

### Background Articles:

- Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann



Intern Med. 2007;147:123-127.

- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med. 2007;147:117-122.
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875.
- Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205.

Available from the [USPSTF Web site](#) .

The following are also available:

- Screening for autism spectrum disorder in young children: clinical summary. Rockville (MD): U.S. Preventive Services Task Force; 2016 Feb. 1 p. Available from the [USPSTF Web site](#) .
- A continuing medical education (CME) activity is available from the [Journal of the American Medical Association \(JAMA\) Web site](#) .

The [Electronic Preventive Services Selector \(ePSS\)](#)  is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

## Patient Resources

The following are available:

- Screening for autism spectrum disorder in young children. Understanding task force recommendations. Rockville (MD): U.S. Preventive Services Task Force. 2016 Feb. 4 p. Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#) .
- Screening for autism spectrum disorder. Journal of the American Medical Association (JAMA) patient page. JAMA. 2016 Feb 16;315(7):718. Available in [English](#)  and [Spanish](#)  from the JAMA Web site.

Myhealthfinder is a tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at [www.healthfinder.gov](http://www.healthfinder.gov)

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Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

This NGC summary was completed by ECRI Institute on April 8, 2016. The information was verified by the guideline developer on May 3, 2016.

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